UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

Anthony Woodard, Individually and as Executor of the Estate of JD Woodard, Plaintiff, v. JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON and JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC, JANSSEN ORTHO LLC, JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER PHARMA AG, BAYER CORPORATION BAYER HEALTHCARE LLC, BAYER HEALTHCARE AG, and BAYER AG, Defendants.	*	CIVIL ACTION NO.:_____ COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff Anthony Woodard, Individually and as Executor of the Estate of JD Woodard (hereinafter "Plaintiff) by and through his undersigned counsel, upon information and belief, at all times hereinafter mentioned, alleges as follows:

PARTIES AND CITIZENSHIP

1. Plaintiff Anthony Woodard, at all times relevant hereto, is a citizen and resident of the State of North Carolina and is Executor of the Estate of JD Woodard, his deceased father.

2. Plaintiff's Decedent, JD Woodard, was, at all times relevant herein, an adult citizen and resident of Wilson County, North Carolina. Mr. Woodard died on June 16, 2013 at Vidant Medical Center in Pitt County, North Carolina.

3. Upon information and belief, Plaintiff's Decedent was prescribed Xarelto in the State of North Carolina, on or from March 2013 through June 2013, upon direction of his physician, Dr. James Smith, for the treatment of a deep vein thrombosis.

4. Upon information and belief, Plaintiff's Decedent first began using Xarelto on or about March 1, 2013, and used Xarelto through his hospitalization on June 11, 2013.

5. Upon information and belief, as a direct and proximate result of the use of Defendants' Xarelto, Plaintiff's Decedent experienced a life-threatening gastrointestinal hemorrhage requiring blood transfusions and an extensive hospitalization, which resulted in his death on or about June 16, 2013.

6. Upon information and belief, Defendant JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON RESEARCH AND DEVELOPMENT LLC (hereinafter referred to as "JANSSEN R&D") is a limited liability company organized under the laws of New Jersey, with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey, 08933. Defendant JANSSEN R&D is the holder of the approved New Drug Application ("NDA") for Xarelto as well as the supplemental NDA.

7. As part of its business, JANSSEN R&D is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto and rivaroxaban.

8. Upon information and belief, Defendant JANSSEN R&D has transacted and conducted business in the State of North Carolina.

9. Upon information and belief, Defendant JANSSEN R&D has derived substantial revenue from goods and products used in the State of North Carolina.

10. Upon information and belief, Defendant JANSSEN R&D expected or should have expected its acts to have consequences within the United States of American and the State of North Carolina, and derived substantial revenue from interstate commerce within the United States and the State of North Carolina.

11. Upon information and belief, and at all relevant times, Defendant JANSSEN R&D was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

12. Upon information and belief, Defendant JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA INC., f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. (hereinafter referred to as "JANSSEN PHARM") is a Pennsylvania corporation, having its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

13. As part of its business, JANSSEN PHARM is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto and rivaroxaban.

14. Upon information and belief, Defendant JANSSEN PHARM, has transacted and conducted business in the State of North Carolina.

15. Upon information and belief, Defendant JANSSEN PHARM, has derived substantial revenue from goods and products used in the State of North Carolina.

16. Upon information and belief, Defendant JANSSEN PHARM, expected or should have expected its acts to have consequence within the United States of American and the State of North Carolina, and derived substantial revenue from interstate commerce within the United States and the State of North Carolina.

17. Upon information and belief, and at all relevant times, Defendant JANSSEN PHARM, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

18. Upon information and belief, Defendant JANSSEN ORTHO LLC. (hereinafter referred to as "JANSSEN ORTHO") is a limited liability company organized under the laws of Delaware, having as principal place of business at State Road 933 Km 0 1, Street Statero, Gurabo, Puerto Rico 00778. Defendant JANSSEN ORTHO is a subsidiary of Johnson & Johnson.

19. As part of its business, JANSSEN ORTHO is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto and rivaroxaban.

20. Upon information and belief, Defendant JANSSEN ORTHO has transacted and conducted business in the State of North Carolina.

21. Upon information and belief, Defendant JANSSEN ORTHO, has derived substantial revenue from goods and products used in the State of North Carolina.

22. Upon information and belief, Defendant, JANSSEN ORTHO, expected or should have expected its acts to have consequences within the United States of America and the State of North Carolina, and derived substantial revenue from interstate commerce within the United States and the State of North Carolina.

23. Upon information and belief, and at all relevant times, Defendant, JANSSEN ORTHO, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrent of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

24. Upon information and belief, Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. is, and at all relevant times was, a corporation organized under the laws of the State of Delaware, with its principal place of business in the State of New Jersey.

25. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. was formerly known as Berlex Laboratories, Inc., which was formerly known as Berlex, Inc. and BAYER HEALTHCARE PHARMACEUTICALS, INC. is the same corporate entity as Berlex, Inc. and Berlex Laboratories, Inc.

26. As part of its business, BAYER HEALTHCARE PHARMACEUTICALS, INC. is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto and rivaroxaban.

27. Upon information and belief, Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC. has transacted and conducted business in the State of North Carolina.

28. Upon information and belief, Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., has derived substantial revenue from goods and products used in the State of North Carolina.

29. Upon information and belief, Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., expected or should have expected its acts to have consequences within the United States of America and the State of North Carolina, and derived substantial revenue from interstate commerce within the United States and the State of North Carolina.

30. Upon information and belief, and at all relevant times, Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

31. Upon information and belief, Defendant BAYER PHARMA AG is a pharmaceutical company domiciled in Germany.

32. Defendant BAYER PHARMA AG is formerly known as Bayer Schering Pharma AG and is the same corporate entity as Bayer Schering Pharma AG. Bayer Schering Pharma AG is formerly known as Schering AG and is the same corporate entity as Schering AG.

33. Upon information and belief, Schering AG was renamed Bayer Schering Pharma AG effective December 29, 2006.

34. Upon information and belief, Schering AG was renamed BAYER PHARMA AG effective July 1, 2011.

35. As part of its business, BAYER PHARMA AG is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto and rivaroxaban.

36. Upon information and belief, Defendant, BAYER PHARMA AG, has transacted and conducted business in the State of North Carolina.

37. Upon information and belief, Defendant, BAYER PHARMA AG, has derived substantial revenue from goods and products used in the State of North Carolina.

38. Upon information and belief, Defendant, BAYER PHARMA AG, expected or should have expected its acts to have consequences within the United States of America and the State of North Carolina, and derived substantial revenue from interstate commerce within the United States and the State of North Carolina.

39. Upon information and belief, and at all relevant times, Defendant, BAYER PHARMA AG, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for patients undergoing hip and knee replacement surgery.

40. Upon information and belief, Defendant BAYER CORPORATION is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

41. Upon information and belief, Defendant BAYER CORPORATION is the sole member of BAYER HEALTHCARE LLC, which owns 100% of Schering Berlin, Inc., which owns 100% of Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. As such,

Defendant BAYER CORPORATION is a parent of Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC.

42. At relevant times, Defendant BAYER CORPORATION was engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Xarelto.

43. At relevant times, Defendant BAYER CORPORATION conducted regular and sustained business in the State of North Carolina, by selling and distributing its products in the State of North Carolina and engaged in substantial commerce and business activity in the State of North Carolina.

44. Upon information and belief, Defendant BAYER HEALTHCARE, LLC is a limited liability company duly formed and existing under and by the virtue of the laws of the State of Delaware, with its principal place of business located in the State of New Jersey.

45. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE LLC has transacted and conducted business in the State of North Carolina, and derived substantial revenue from interstate commerce. Defendant BAYER CORPORATION is the sole member of Defendant BAYER HEALTHCARE, LLC.

46. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE, LLC expected or should have expected that its acts would have consequences within the United States of America and in the State of North Carolina, and derived substantial revenue from interstate commerce.

47. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE, LLC was in the business of and did design, research, manufacture, test,

advertise, promote, market, sell, and distribute Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

48. Upon information and belief, Defendant BAYER HEALTHCARE AG is a company domiciled in Germany and is the parent/holding company of Defendants BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER PHARMA AG.

49. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG has transacted and conducted business in the State of North Carolina, and derived substantial revenue from interstate commerce.

50. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG expected or should have expected that its acts would have consequences within the United States of America, and in the State of North Carolina, and derived substantial revenue from interstate commerce.

51. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG exercises dominion and control over Defendants BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER PHARMA AG.

52. Upon information and belief, Defendant BAYER AG is a German chemical and pharmaceutical company that is headquartered in Leverkusen, North Rhine-Westphalia, Germany.

53. Upon information and belief, and at all relevant times Defendant BAYER AG is parent/holding company of all other named Defendants.

54. Upon information and belief, at all relevant times, Defendant BAYER AG has transacted and conducted business in the State of North Carolina, and derived substantial revenue from interstate commerce.

55. Upon information and belief, at all relevant times, Defendant BAYER AG expected or should have expected that its acts would have consequences within the United States of America, and in the State of North Carolina, and derived substantial revenue from interstate commerce.

56. Upon information and belief, at all relevant times, Defendant BAYER AG was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

JURISDICTION AND VENUE

57. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds, $75,000.000, exclusive of interest and costs, and because there is complete diversity of citizenship between the Plaintiff and the Defendants.

58. Venue of this case is appropriate in the Eastern District Court of State of North Carolina pursuant to 28 U.S.C § 1391 because a substantial part of the events or omissions

giving rise to the claim occurred in this District and because Defendants conduct substantial business in this District.

59. This Court has personal jurisdiction over the Defendants because they have done business in the State of North Carolina, have committed a tort in whole or in part in the State of North Carolina, have substantial and continuing contact with the State of North Carolina, and derive substantial revenue from goods used and consumed within the State of North Carolina. The Defendants actively sell, market, and promote their pharmaceutical product Xarelto to physicians and consumers in this state on a regular and consistent basis.

TAG ALONG ACTION

60. This is a tag along action and in accordance with 28 U.S.C. § 14-7, it should be transferred to the United States District Court of Louisiana for inclusion in *In Re Xarelto (Rivaroxaban) Products Liability Litigation*, MDL #2592 (Hon. Eldon E. Fallon).

NATURE OF THE CASE

61. This action is brought on behalf of Plaintiff Anthony Woodard, Individually, and as Executor of the Estate of JD Woodard. Plaintiff's Decedent used Xarelto, also known as rivaroxaban, which is a medication used to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat deep vein thrombosis (hereinafter referred to as "DVT") and pulmonary embolism (hereinafter referred to as "PE"), to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

62. Defendants, JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC, JANSSEN ORTHO LLC, JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA

INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER PHARMA AG, BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE AG, and BAYER AG (hereinafter collectively referred to as "Defendants") designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Xarelto.

63. When warning of safety and risks of Xarelto, Defendants negligently and/or fraudulently represented to the medical and healthcare community, the Food and Drug Administration (hereinafter referred to as the "FDA"), to Plaintiff's Decedent and the public in general, that Xarelto had been tested and was found to be safe and/or effective for its indicated use.

64. These representations were made by Defendants with the intent of defrauding and deceiving Plaintiff's Decedent, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense and/or purchase Xarelto for use to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Plaintiff's Decedent herein.

65. Defendants negligently and improperly failed to perform sufficient tests, if any, on humans using Xarelto during clinical trials, forcing Plaintiff's Decedent, and Plaintiff's Decedent's physician, hospitals, and/or the FDA, to rely on safety information that applies to other non-valvular atrial fibrillation treatment and DVT/PE treatment and prophylaxis, which does not entirely and/or necessarily apply to Xarelto whatsoever.

66. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff's Decedent and Plaintiff's Decedent's physicians the true and significant risks associated with Xarelto use.

67. As a result of Defendants' actions, Plaintiff's Decedent and Plaintiff's Decedent's physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff's Decedent would be exposed to the risks identified in this Complaint. The increased risks and subsequent medical damages associated with Plaintiff's Decedent's Xarelto use were the direct and proximate result of Defendants' conduct.

68. On or around March 1, 2013, Plaintiff's Decedent, JD Woodard, was first prescribed and began taking Xarelto, upon the direction of his physician, Dr. James Smith. Mr. Woodard was prescribed Xarelto, 20 mg, once daily. Thereafter, as a direct result of Mr. Woodard's ingestion of Xarelto, on June 11, 2013, he was admitted to Vidant Medical Center with a significant gastrointestinal bleed. Plaintiff's Decedent underwent transfusion of blood products but continued to suffer an irreversible bleed, continued to deteriorate, and died on June 16, 2013.

69. Plaintiff's Decedent died as a direct result of exposure to Xarelto.

70. As a proximate result of Defendants' acts and omissions, Plaintiff's Decedent suffered the injuries described hereinabove due to ingestion of Xarelto. Plaintiff accordingly seeks damages associated with these injuries.

FACTUAL BACKGROUND

71. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute Xarelto and rivaroxaban to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation,

to treat DVT and PE, to reduce the risk of recurrent of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

72. Defendants received FDA approval for Xarelto, also known as rivaroxaban, on July 1, 2011 for the prophylaxis of DVT and PE in patients undergoing hip replacement or knee replacement surgeries.

73. Defendants then received additional FDA approval for Xarelto to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation on November 4, 2011.

74. The additional indication for treatment of DVT and/or PE and the reduction in recurrence of DVT and/or PE was added to the label on November 2, 2012.

75. Defendants launched Xarelto in the United States (hereinafter referred to as the "U.S.") in 2011.

76. Xarelto in an anticoagulant that acts as a Factor Xa inhibitor, and is available by prescription in oral tablet doses of 20mg, 15mg, and 10mg.

77. Approval of Xarelto for the prophylaxis of DVT and PE in patients undergoing hip replacement or knee replacement surgeries was based on a series of clinical trials known as the Regulation of Coagulation in Orthopedic Surgery to Prevent Deep Venous Thrombosis and Pulmonary Embolism studies (hereinafter referred to as the "RECORD" studies). The findings of the RECORD studies show that rivaroxaban was superior to enoxaparin for thromboprophylaxis after total knee and hip arthroplasty (bases on the Defendants' definition), accompanied by similar rates of bleeding. However, the studies also showed a greater incidence with Xarelto of bleeding leading to decreased hemoglobin levels and transfusion of blood. (Lassen, M.R., et al. *Rivaroxaban versus Enoxaparin for Thromboprophylaxis after Total Knee*

Arthroplasty. N.Engl.J.Med. 2008;358:2776-86; Kakkar, A.K., et al. *Extended duration rivaroxaban versus short-term enoxaparin for the prevention of venous thromboembolism after total hip arthroplasty*; *a double-blind, randomized controlled trial*. Lancet 2008; 372:31-39; Ericksson, B.I., et al. *Rivaroxaban versus Enoxaparin for Thromboprophylaxis after Hip Arthroplasty*. N.Engl.J.Med. 2008; 358:2765-75.)

78. Approval of Xarelto for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation in the U.S. was based on a clinical trial known as the Rivaroxaban Once Daily Oral Direct Factor Xa Inhibition Compared with Vitamin K Antagonism for Prevention of Stroke and Embolism Trial in Atrial Fibrillation study (hereinafter referred to as "ROCKET AF"). The study's findings showed that rivaroxaban was non-inferior to warfarin for the prevention of stroke or systemic embolism in patients with non-valvular atrial fibrillation, with a similar risk of major bleeding. However, "bleeding from gastrointestinal sites, including upper, lower, and rectal sites, occurred more frequently in the rivaroxaban group, as did bleeding that led to a drop in the hemoglobin level or bleeding that required transfusion." (Patel, M.R., et al. *Rivaroxaban versus Warfarin in Nonvalvular Atrial Fibrillation*. N.Engl.J.Med. 201 1;365:883-91.)

79. Approval of Xarelto for the treatment of DVT and/or PE and the reduction in recurrence of DVT and/or PE in the U.S. was based on the clinical trials known as EINSTEIN-DVT, EINSTEIN-PE, and EINSTEIN-Extension studies. The EINSTEIN-DVT study tested Xarelto versus a placebo, and merely determined that Xarelto offered an option for treatment of DVT, with obvious increased risk of bleeding events as compared to placebo. (The EINSTEIN Investigators. *Oral Rivaroxaban for Symptomatic Venous Thromboembolism*. N.Engl.J.Med. 201;363:2499-510). The EINSTEIN-Extension study confirmed that result. (Roumualdi, E., et

al. *Oral rivaroxaban after symptomatic venous thromboembolism*: *the continued treatment study* (*EINSTEIN-Extension study*). Expert Rev. Cardiovasc. Ther. 2011;9(7):841-844). The EINSTEIN-PE study's findings showed that a rivaroxaban regimen was non-inferior to the standard therapy for initial and long-term treatment of PE. However, the studies also demonstrated an increased risk of adverse events with Xarelto, including those that resulted in permanent discontinuation of Xarelto or prolonged hospitalization. (THE EINSTEIN-PE Investigators. *Oral Rivaroxaban for the Treatment of Symptomatic Pulmonary Embolism*. N.Engl.J.Med. 2012;366: 1287097.)

80. Defendants use the results of the ROCKET AF study, the RECORD studies, and the EINSTEIN studies to promote Xarelto in their promotional materials, including the Xarelto website, which tout the positive results of those studies. However, Defendants' promotional materials fail to similarly highlight the increased risk of gastrointestinal bleeding and bleeding that required transfusion, among other serious bleeding concerns.

81. Defendants market Xarelto as a new oral anticoagulant treatment alternative to warfarin (Coumadin), a long-established safe treatment for preventing stroke and systemic embolism, in 60 years. Defendants emphasize the supposed benefits of treatment with Xarelto over warfarin, which they refer to as the Xarelto Difference – namely, that Xarelto does not require periodic monitoring with blood tests and does not limit a patient's diet. However, in its QuarterWatch publication for the first quarter of 2012 fiscal year, the Institute for Safe Medication Practices ("ISMP") noted that, even during the approval process, FDA "[r]eviewers also questioned the convenient once-a-day dosing scheme [of Xarelto], saying blood level studies had shown peaks and troughs that could be eliminated by twice-a-day dosing."

82. Importantly, there is no antidote to Xarelto, unlike warfarin. Therefore, in the event of hemorrhagic complication, there is no available reversal agent. The original U.S. label approved when the drug was first marketed in the U.S. did not contain a warning regarding the lack of antidote, but instead only mentioned this important fact in the overdosage section.

83. Defendants spent significant money in promoting Xarelto, which included at least $11,000,000.00 spent during 2013 alone on advertising in journals targeted at prescribers and consumers in the U.S. In the third quarter of the 2013 fiscal year, Xarelto was the number one pharmaceutical product advertised in professional health journals based on pages and dollars spent.

84. As a result of Defendants' aggressive marketing efforts, in its first full year of being on the market, Xarelto garnered approximately $582 million in sales globally.

85. Defendants' website for Xarelto claims that over seven million people worldwide have been prescribed Xarelto. In the U.S., approximately 1 million Xarelto prescriptions had been written by the end of 2013.

86. During the Defendants' 2012 fiscal year, Xarelto garnered approximately $658 million in sales worldwide. Then, in 2013, sales for Xarelto increased even further to more than clear the $1 billion threshold commonly referred to as "blockbuster" status in the pharmaceutical industry, ultimately reaching approximately $2 billion for the fiscal year. Thus, Xarelto is now considered the leading anticoagulant on a global scale in terms of sales.

87. As part of their marketing of Xarelto, Defendants widely disseminated direct-to-consumer advertising campaigns that were designed to influence patients, including Plaintiff's Decedent, to make inquiries to their prescribing physician about Xarelto and/or request prescriptions for Xarelto.

88. In the course of these direct to consumer advertisements, Defendants overstated the efficacy of Xarelto with respect to preventing stroke and systematic embolism, failed to adequately disclose to patients that there is no drug, agent, or means to reverse the anticoagulation effects of Xarelto, and that such irreversibility could have permanently disabling, life-threatening and fatal consequences.

89. On June 6, 2013, Defendants received an untitled letter from the FDA's Office of Prescription Drug Promotion (hereinafter referred to as the "OPDP") regarding its promotional material for the atrial fibrillation indication, stating that, "the print ad is false or misleading because it minimizes the risks associated with Xarelto and makes a misleading claim" regarding dose adjustments, which was in violation of FDA regulations. The OPDP thus requested that Defendants immediately cease distribution of such promotional material.

90. Prior to Plaintiff's Decedent's prescription of Xarelto, Plaintiff's Decedent became aware of the promotional materials described herein.

91. Prior to Plaintiff's Decedent's prescription of Xarelto, Plaintiff's Decedent's prescribing physician received promotional materials and information from sales representatives of Defendants that Xarelto was just as effective as warfarin in reducing strokes in patients with non-valvular atrial fibrillation, as well as preventing DVT/PE in patients with prior history of DVT/PE or undergoing hip or knee replacement surgery, and was more convenient, without also adequately informing prescribing physicians that there was no reversal agent that could stop or control bleeding in patients taking Xarelto.

92. At all times relevant hereto, Defendants also failed to warn emergency room doctors, surgeons, and other critical care medical professionals that unlike generally-known measures taken to treat and stabilize bleeding in users of warfarin, there is no effective agent to

reverse the anticoagulation effects of Xarelto, and therefore no effective means to treat and stabilize patients who experience uncontrolled bleeding while taking Xarelto.

93. At all times relevant to this action, The Xarelto Medication Guide, prepared and distributed by Defendants and intended for U.S. patients to whom Xarelto has been prescribed, failed to warn and disclose to patients that there was no agent to reverse the anticoagulation effects of Xarelto and that if serious bleeding occurs, it may be irreversible, permanently disabling, and life-threatening.

94. In the year leading up to June 30, 2012, there were 1,080 Xarelto-associated "Serious Adverse Event" ("SAE") Medwatch reports filed with the FDA, including at least 65 deaths. Of the reported hemorrhage events associated with Xarelto, 8% resulted in death, which was approximately twofold the risk of hemorrhage-related death with warfarin.

95. At the close of the 2012 fiscal year, a total of 2,081 new Xarelto-associated SAE reports were filed with the FDA in its first full year on the market, ranking tenth among other pharmaceuticals in direct reports to the FDA. Of those reported events, 151 resulted in death, as compared to only 56 death associated with warfarin.

96. The ISMP referred to these SAE figures as constituting a "strong signal" regarding the safety of Xarelto, defined as "evidence of sufficient weight to justify an alert to the public and the scientific community, and to warrant further investigation."

97. Of particular note, in the first quarter of 2013, the number of reported serious adverse events associated with Xarelto (680) overtook that of Pradaxa (528), another new oral anticoagulant, which had previously ranked as the number one reported drug in terms of adverse events of 2012.

98. Moreover, on a global scale, in the first eight months of 2013, German regulators received 968 Xarelto-related adverse events reports, including 72 deaths, as compared to a total of 750 reports and 58 deaths in 2012.

99. Despite the clear signal generated by the SAE data, Defendants failed to either alert the public the scientific community, or perform further investigation into the safety of Xarelto.

100. Defendants original, and in some respects current, labeling and prescribing information for Xarelto:

(a) Failed to investigate, research, study and define, fully and adequately, the safety profile of Xarelto;

(b) Failed to provide adequate warnings about the true safety risks associated with the use of Xarelto;

(c) Failed to provide adequate warning regarding the pharmacokinetic and pharmacodynamic variability of Xarelto and its effects on the degree of anticoagulation in a patient;

(d) Failed to provide adequate warning that it is difficult or impossible to assess the degree and/or extent of anticoagulation in patients taking Xarelto;

(e) Failed to disclose in the "Warnings" Section that there was no drug, agent or means to reverse the anticoagulation effects of Xarelto;

(f) Failed to advise prescribing physicians, such as the Plaintiff's Decedent's physician, to instruct patients that there was no agent to reverse the anticoagulant effects of Xarelto;

(g) Failed to provide adequate instructions on how to intervene and/or stabilize a patient who suffers a bleed while taking Xarelto;

(h) Failed to provide adequate warning and information related to the increased risks of bleeding events associated with aging patient populations of Xarelto users;

(i) Failed to provide adequate warnings regarding the increased risk of gastrointestinal bleeds in those taking Xarelto, especially, in those patients with a prior history of gastrointestinal issues and/or upset;

(j) Failed to provide adequate warning regarding the increased risk of suffering a bleeding event, requiring blood transfusions in those taking Xarelto;

(k) Failed to provide adequate warnings regarding the need to assess renal functioning prior to starting a patient on Xarelto and to continue testing and monitoring of renal functioning periodically while the patient is on Xarelto;

(l) Failed to provide adequate warnings regarding the need to assess hepatic functioning prior to starting a patient on Xarelto and to continue testing and monitoring of hepatic functioning periodically while the patient is on Xarelto;

(m) Failed to provided adequate warnings that regular monitoring while the patient is on Xarelto is necessary to prevent excessive and dangerous bleeding, including but not limited to blood tests such as a prothrombin time, or an anti-Factor Xa chromogenic assay;

(n) Failed to include a **"BOXED WARNING"** about serious bleeding events associated with Xarelto;

(o) Failed to include a **"BOLDED WARNING"** about serious bleeding events associated with Xarelto; and

(p) In their "Medication Guide" intended for distribution to patients to whom Xarelto has been prescribed, Defendants failed to disclose to patients that there is no drug, agent or means to reverse the anticoagulation effects of Xarelto and that if serious bleeding occurs, such irreversibility could be permanently disabling, life-threatening or have fatal consequences.

101. During the years since first marketing Xarelto in the U.S., Defendants modified the U.S. labeling and prescribing information for Xarelto, which included additional information regarding the use of Xarelto in patients taking certain medications. Despite being aware of: (1) serious, and sometimes fatal, irreversible bleeding events associated with the use of Xarelto; and (2) 2,081 SAE Medwatch reports filed with the FDA in 2012 alone, including at least 151 deaths, Defendants nonetheless failed to provide adequate disclosures or warning in their label as detailed in Paragraph 100.

102. Prior to applying for and obtaining approval of Xarelto, Defendants knew or should have know that consumption of Xarelto was associated with and/or would cause the

induction of life-threatening bleeding, and Defendants possessed at least one clinical scientific study, which evidences that Defendants knew or should have known was a signal that life-threatening bleeding risk needed further testing and studies prior to its introduction to the market.

103. Upon information and belief, despite life-threatening bleeding findings in a clinical trial and other clinical evidence, Defendants failed to adequately conduct complete and proper testing of Xarelto prior to filing their New Drug Application of Xarelto.

104. Upon information and belief, from the date Defendants received FDA approval to market Xarelto, Defendants made, distributed, marketed, and sold Xarelto without adequate warning to Plaintiff's Decedent's prescribing physicians or Plaintiff's Decedent that Xarelto was associated with and/or could cause life-threatening bleeding, presented a risk of life-threatening bleeding in patients who used it, and that Defendants had not adequately conducted complete and proper testing and studies of Xarelto with regard to several side effects, specially life-threatening bleeding.

105. Upon information and belief, Defendants concealed and failed to completely disclose its knowledge that Xarelto was associated with or could cause life-threatening bleeding as well as its knowledge that they had failed to fully test or study said risk.

106. Upon information and belief, Defendants ignored the association between the use of Xarelto and the risk of developing life-threatening bleeding.

107. Defendants' failure to disclose information that they possessed regarding the failure to adequately test and study Xarelto for life-threatening bleeding risk further rendered warnings for this medication inadequate.

108. By reason of the foregoing acts and omissions, the Plaintiff's Decedent was caused to suffer a life threatening bleed resulting in death, physical pain and mental anguish,

including diminished enjoyment of his remaining life, expenses for hospitalization and medical treatment, and loss of earnings.

AS A FIRST CAUSE OF ACTION: NEGLIGENCE

109. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

110. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sales and/or distribution of Xarelto into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

111. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Xarelto into interstate commerce in that Defendants knew or should have known that using Xarelto created a high risk of unreasonable, dangerous side effects, including life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, expenses for hospitalization and medical treatment, and loss of earnings.

112. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) Manufacturing, producing, promoting, formulating, creating, and/or designing Xarelto without thoroughly testing it;

(b) Manufacturing, producing, promoting, formulating, creating, and/or designing Xarelto without adequately testing it;

(c) Not conducting sufficient testing programs to determine whether or not Xarelto was safe for use; in that Defendants herein knew or should have known that Xarelto was unsafe and unfit for use by reason of the dangers to its users;

(d) Selling Xarelto without making proper and sufficient tests to determine the dangers to its users;

(e) Negligently failing to adequately and correctly warn the Plaintiff's Decedent, the public, the medical and healthcare profession, and the FDA of the dangers of Xarelto;

(f) Failing to provide adequate instructions regarding safety and foreseeably come into contact with, and more particularly, use, Xarelto;

(g) Failing to test Xarelto and/or failing to adequately, sufficiently and properly test Xarelto;

(h) Negligently advertising and recommending the use of Xarelto without sufficient knowledge as to its dangerous propensities;

(i) Negligently representing that Xarelto was safe for use for its intended purpose, when, in fact, it was unsafe;

(j) Negligently representing that Xarelto had equivalent safety and efficacy as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

(k) Negligently designing Xarelto in a manner which was dangerous to its users;

(l) Negligently manufacturing Xarelto in a manner which was dangerous to its users;

(m) Negligently producing Xarelto in a manner which was dangerous to its users;

(n) Negligently assembling Xarelto in a manner which was dangerous to its users;

(o) Concealing information from the Plaintiff's Decedent in knowing that Xarelto was unsafe, dangerous, and/or non-conforming with FDA regulations;

(p) Improperly concealing and/or misrepresenting information from the Plaintiff's Decedent, healthcare professionals, and/or the FDA, concerning the severity of risks and dangers of Xarelto compared to other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery; and

(q) Improperly concealing and/or misrepresenting information from the Plaintiff's Decedent, healthcare professionals, and/or the FDA that routine monitoring or blood tests were necessary.

113. Defendants under-reported, underestimated and downplayed the serious dangers of Xarelto.

114. Defendants negligently compared the safety risk and/or dangers of Xarelto with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

115. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of Xarelto in that they:

(a) Failed to use due care in designing and manufacturing Xarelto so as to avoid the aforementioned risks to individuals when Xarelto was used for treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

(b) Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of Xarelto;

(c) Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of Xarelto;

(d) Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning Xarelto;

(e) Failed to warn Plaintiff's Decedent of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

(f) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Xarelto;

(g) Failed to warn Plaintiff's Decedent, prior to actively encouraging the sale of Xarelto, either directly or indirectly, orally or in writing, about the need for more

comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects;

(h) Failed to warn Plaintiff's Decedent, that routine mentoring or blood tests including but not limited to a prothrombin time or an anti-factor XA chromogenic assay was necessary; and

(i) Were otherwise careless and/or negligent.

116. Despite the fact that Defendants knew or should have know that Xarelto caused unreasonably dangerous side effects, Defendants continued and continue to market, manufacture, distribute and/or sell Xarelto to consumers, including the Plaintiff's Decedent.

117. Defendants knew or should have known that consumers such as the Plaintiff's Decedent would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

118. Defendants' negligence was the proximate cause of injuries, harm and economic loss, which Plaintiff's Decedent suffered.

119. As a result of the foregoing acts and commissions, Plaintiff's Decedent was caused to suffer serious and dangerous side effects including a life-threatening bleed resulting in death, physical pain and mental anguish, diminished enjoyment of life, expenses for hospitalization and medical treatment, and loss of earnings.

120. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

AS A SECOND CAUSE OF ACTION: DEFECTIVE MANUFACTURING

121. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

122. Defendants were and are engaged in the business of selling Xarelto in the State of North Carolina.

123. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have recently acquired the Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed Xarelto as hereinabove described that was used by the Plaintiff's Decedent.

124. That Xarelto was expected to and did reach Plaintiff's Decedent and the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

125. At those times, Xarelto was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff's Decedent herein.

126. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of Xarelto.

127. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design and/or formulation, in that, when it left the hands of the Defendants, manufacturers, and/or supplies, it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.

128. At all times herein mentioned, Xarelto was in a defective condition and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants.

129. Defendants knew, or should have known that at all times herein mentioned, their Xarelto was in a defective condition, and was and is inherently dangerous and unsafe.

130. At the time of the Plaintiff's Decedent's use of Xarelto, Xarelto was being used for the purposes and in a manner normally intended, namely to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to reduce the risk of recurrence of DVT and/or PE, ad for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

131. Defendants with this knowledge voluntarily designed Xarelto in a dangerous condition for use by the public, and in particular the Plaintiff's Decedent.

132. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

133. Defendants created a product unreasonably dangerous for its normal, intended use.

134. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was manufactured defectively in that Xarelto left the hands of Defendants in a defective condition was unreasonably dangerous to its intended users.

135. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended uses in the same defective and unreasonably dangerous condition in which the Defendants' Xarelto was manufactured.

136. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have know of the risks of serious side effects including, life-threatening bleeding, as well as other severe and permanent health consequences from Xarelto, they failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote their product, Xarelto.

137. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

AS A THIRD CAUSE OF ACTION: DEFECTIVE DESIGN

138. Plaintiff repeats, reiterates and re-alleges each every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

139. Defendants were and are engaged in the business of selling Xarelto in the State of North Carolina.

140. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

141. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have recently acquired the Defendants who have designed, researched, manufactured, tested, advertised promoted, marketed, sold and distributed Xarelto as hereinabove that was used by the Plaintiff's Decedent.

142. That Xarelto was expected to and did reach Plaintiff's Decedent and the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

143. At those times, Xarelto was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff's Decedent herein.

144. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of Xarelto.

145. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design and/or formulation, in that, when it left the hands of the Defendants, manufacturers, and/or suppliers, it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.

146. At all times herein mentioned, Xarelto was in a defective condition and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants.

147. Defendants knew, or should have known that at all times herein mentioned, their Xarelto was in a defective condition, and was and is inherently dangerous and unsafe.

148. At the time of the Plaintiff's Decedent's use of Xarelto, Xarelto was being used for the purposes and in the manner normally intended, namely to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to reduce the risk of

recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

149. Defendants with this knowledge voluntarily designed its Xarelto in a dangerous condition for use by the public, and in particular the Plaintiff's Decedent.

150. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

151. Defendants created a product unreasonably dangerous for its normal, intended use.

152. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was manufactured defectively in that Xarelto left the hands of Defendants in a defective condition and was unreasonably dangerous to its intended users.

153. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' Xarelto was manufactured.

154. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks or serious side effects including, life-threatening bleeding, as well as other severe and permanent health consequences from Xarelto, they failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote their product, Xarelto.

155. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

AS A FOURTH CAUSE OF ACTION: FAILURE TO ADEQUATELY TEST

156. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth therein.

157. Defendants advised and suggested to consumers and the medical community that Xarelto had been adequately tested and was safe for use.

158. The Plaintiff's Decedent could not, by the exercise of reasonable care, have discovered Xarelto's defects herein mentioned and perceived its danger.

159. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings and/or inadequate testing.

160. Had Defendants adequately tested the safety of Xarelto as it pertains to life-threatening bleeding, as well as other severe and permanent health consequences and disclosed those results to the medical community or the public, Plaintiff's Decedent would not have ingested Xarelto.

161. As a direct and proximate result of Defendants' negligence and failure to adequately test the safety of Xarelto, Plaintiff's Decedent sustained injuries as described herein.

162. As a result of the foregoing acts and commissions, Plaintiff's Decedent was caused to suffer serious and dangerous side effects including a life-threatening bleed resulting in death, physical pain and mental anguish, diminished enjoyment of life, expenses for hospitalization and medical treatment, and loss of earnings.

163. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

AS A FIFTH CAUSE OF ACTION: FAILURE TO WARN

164. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

165. Xarelto® was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert patients and prescribing physicians of the dangerous risks and reactions associated with Xarelto®, including but not limited to the prevalence of irreversible bleeding, and other serious injuries and side effects despite the Defendant's knowledge of the increased risk of these injuries over other anticoagulation therapies available.

166. Xarelto® was defective due to inadequate post-marketing warnings and instruction because Defendants knew or should have known of the risk and danger of serious bodily harm and/or death from the use of Xarelto® but failed to provide an adequate warning to patients and prescribing physicians of the product, knowing the product could cause serious injury or death.

167. Plaintiff's Decedent was prescribed and used Xarelto for its intended purpose and could not have known about the dangers and hazards presented by Xarelto through the exercise of reasonable care.

168. The warnings that were given by the Defendants were not accurate, clear, compete, and/or were ambiguous.

169. The warnings, or lack thereof, that were given by the Defendants failed to properly warn prescribing physicians of the risk of irreversible bleeding and other serious injuries and side effects, and failed to instruct prescribing physicians to test and monitor for the presence of the injuries for which Plaintiff's Decedent and others had been placed at risk.

170. The warnings that were given by the Defendants failed to properly warn the ingesting Plaintiff and prescribing physicians of the prevalence of irreversible bleeds. Plaintiff's Decedent did not have the same knowledge as Defendants and no adequate warning was communicated to his physicians(s).

171. The warnings that were given failed to provide adequate warnings regarding the need to assess renal functioning prior to starting a patient on Xarelto and to continue testing and monitoring of renal functioning periodically while the patient is on Xarelto.

172. The warnings that were given failed to provide adequate warnings regarding the need to assess hepatic functioning prior to starting a patient on Xarelto and to continue testing and monitoring of hepatic functioning periodically while the patient is on Xarelto.

173. The warnings that were given failed to provide adequate warnings regarding the need for routine monitoring or blood tests including, but not limited to a prothrombin time, or an anti-Factor Xa chromogenic assay while the patient was on Xarelto.

174. Plaintiff's Decedent, individually and through his prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of the Defendants. The Defendants had a continuing duty to warn the ingesting Plaintiff's Decedent and prescribing physicians of the dangers associated with Xarelto®. Had Plaintiff's Decedent received adequate warnings regarding the risks of Xarelto®, he would not have used Xarelto®.

175. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce the pharmaceutical, Xarelto, and in the course of same, directly advertised or marketed the product to consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of Xarelto.

176. The promotional activities of Defendants further diluted or minimized the warnings given with the product.

177. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field and, further, Defendants had knowledge of the dangerous risks and side effects of Xarelto.

178. Defendants had a continuing duty to warn consumers, including Plaintiff's Decedent and his physicians, and the medical community of the dangers associated with Xarelto, and by negligently and/or wantonly failing to adequately warn of the dangers associated with its use, Defendants breached their duty.

179. Although Defendant knew, or were reckless in not knowing, of the defective nature of Xarelto, they continued to design, manufacture, market, and sell Xarelto without providing adequate warnings and instructions concerning the use of Xarelto so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by Xarelto.

180. As a result of the foregoing acts and commissions, Plaintiff's Decedent was caused to suffer serious and dangerous side effects including a life-threatening bleed resulting in death, physical pain and mental anguish, diminished enjoyment of life, expenses for hospitalization and medical treatment, and loss of earnings.

181. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

AS A SIXTH CAUSE OF ACTION: BREACH OF EXPRESS WARRANTY

182. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully herein. Defendants expressly warranted that Xarelto was safe and well accepted by users and that routine monitoring or blood tests were not necessary. Xarelto does not conform to these express representations because Xarelto is not safe and has numerous side effects, many of which were not accurately about by Defendants. Additionally, monitoring and blood tests including but not limited to a prothrombin time or an anti-Factor Xa Chromogenic assay are necessary.

183. As a direct and proximate result of the breach of said warranties, Plaintiff's Decedent suffered severe personal injuries, death and economic loss.

184. Plaintiff's Decedent did rely on the express warranties of the Defendants herein.

185. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of Xarelto in recommending, prescribing, and/or dispensing Xarelto.

186. The Defendants herein breached the aforesaid express warranties, as their drug Xarelto was defective.

187. Defendants expressly represented to Plaintiff's Decedent, Plaintiff's Decedent's physicians, healthcare providers, and/or the FDA that Xarelto was safe and fit for use for the purposes intended, that it was merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for reducing the risk of

stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

188. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Xarelto was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

189. As a result of the foregoing acts and commissions, Plaintiff's Decedent was caused to suffer serious and dangerous side effects including a life-threatening bleed resulting in death, physical pain and mental anguish, diminished enjoyment of life, expenses for hospitalization and medical treatment, and loss of earnings.

190. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

AS A SEVENTH CAUSE OF ACTION: BREACH OF IMPLIED WARRANTIES

191. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

192. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Xarelto and/or have recently acquired the Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Xarelto, to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat

DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

193. At the time Defendants marketed, sold, and distributed Xarelto for use by Plaintiff's Decedent, Defendants knew of the use for which Xarelto was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

194. The Defendants impliedly represented and warranted to the users of Xarelto and their physicians, healthcare providers, and/or the FDA that Xarelto was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

195. That said representations and warranties aforementioned were false, misleading, and inaccurate in that Xarelto was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

196. Plaintiff's Decedent, and/or members of the medical community and/or healthcare professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

197. Plaintiff's Decedent and Plaintiff's Decedent's physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether Xarelto was of merchantable quality and safe and fit for its intended use.

198. Xarelto was injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

199. The Defendants herein breach the aforesaid implied warranties, as their drug Xarelto was not fit for its intended purposes and uses.

200. As a result of the foregoing acts and commissions, Plaintiff's Decedent was caused to suffer serious and dangerous side effects including a life-threatening bleed resulting in death, physical pain and mental anguish, diminished enjoyment of life, expenses for hospitalization and medical treatment, and loss of earnings.

201. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

AS AN EIGHTH CAUSE OF ACTION: FRAUDULENT MISREPRESENTATION

202. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

203. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff's Decedent, and/or the FDA, and the public in general, that said product, Xarelto, had been tested and was found to be safe and/or effective to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery and that no monitoring or blood tests were necessary.

204. That representations made by Defendants were, in fact, false.

205. When said representations were made by Defendants, they knew those representations to be false and willfully, wantonly and recklessly disregarded whether the representations were true.

206. These representations were made by said Defendants with the intent of defrauding and deceiving the Plaintiff's Decedent, the public in general, and the medical and healthcare

community in particular, and were made with the intent of inducing the public in general, and the medical healthcare community in particular, to recommend, prescribe, dispense and/or purchase said product, Xarelto, for use to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff's Decedent and Plaintiff herein.

207. At the time of the aforesaid representations were made by the Defendants and, at the time the Plaintiff's Decedent used Xarelto, the Plaintiff's Decedent was unaware of the falsity of said representations and reasonably believed them to be true.

208. In reliance upon said representations, the Plaintiff's Decedent was induced to and did use Xarelto, thereby sustaining severe and permanent personal injuries.

209. Said Defendants knew and were aware of should have been aware that Xarelto had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

210. Defendants knew or should have known that Xarelto had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

211. Defendants brought Xarelto to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff's Decedent.

212. As a result of the foregoing acts and commissions, Plaintiff's Decedent was caused to suffer serious and dangerous side effects including a life-threatening bleed resulting in

death, physical pain and mental anguish, diminished enjoyment of life, expenses for hospitalization and medical treatment, and loss of earnings.

213. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

AS AN NINTH CAUSE OF ACTION: FRAUDULENT CONCEALMENT

214. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

215. At all times during the course of dealing between Defendants and Plaintiff's Decedent, and/or Plaintiff's Decedent's healthcare providers, and/or the FDA, Defendants misrepresented the safety of Xarelto for its intended use.

216. Defendants knew or were reckless in not knowing that their representations were false.

217. In representations to Plaintiff's Decedent, and/or Plaintiff's Decedent's healthcare providers, and/or the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

(a) That Xarelto was not as safe as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

(b) That the risks of adverse events with Xarelto were higher than those with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

(c) That the risks of adverse events with Xarelto were not adequately tested and/or known by Defendants;

(d) That Defendants were aware of dangers in Xarelto, in addition to and above and beyond those associated with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

(e) That Xarelto was defective, and that it caused dangerous side effects, including but not limited to life-threatening bleeding, as well as other severe and permanent health consequences, in a much more and significant rate than other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

(f) That patients needed to be monitored more regularly than normal while using Xarelto, and that routine blood tests are necessary;

(g) That Xarelto was manufactured negligently;

(h) That Xarelto was manufactured defectively;

(i) That Xarelto was manufactured improperly;

(j) That Xarelto was designed negligently;

(k) That Xarelto was designed defectively; and

(l) That Xarelto was designed improperly.

218. Defendants were under a duty to disclose to Plaintiff's Decedent, and Plaintiff's Decedent's physicians, hospitals, healthcare providers, and/or the FDA the defective nature of Xarelto, including but not limited to the heightened risks of life-threatening bleeding.

219. Defendants had sold access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used Xarelto, including the Plaintiff's Decedent.

220. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of Xarelto was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff's Decedent, and Plaintiff's Decedent's physicians, hospitals and healthcare providers

into reliance, continued use of Xarelto, and actions thereon, and to cause them to purchase, prescribe and/or dispense Xarelto and/or use the product.

221. Defendants knew that Plaintiff's Decedent, and Plaintiff's Decedent's physicians, hospitals, healthcare providers and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Xarelto, as set forth herein.

222. Plaintiff's Decedent, as well as Plaintiff's Decedent's doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

223. As a result of the foregoing acts and commissions, Plaintiff's Decedent was caused to suffer serious and dangerous side effects including a life-threatening bleed resulting in death, physical pain and mental anguish, diminished enjoyment of life, expenses for hospitalization and medical treatment, and loss of earnings.

224. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

AS AN TENTH CAUSE OF ACTION: NEGLIGENT MISREPRSENTATION

225. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

226. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff's Decedent, the FDA, and the public in general that said product, Xarelto, had been tested and found to be safe and effective to reduce the risk of stroke and systemic embolism

in patients with non-valvular atrial fibrillation, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

227. The representations made by Defendants were, in fact, false.

228. Defendants failed to exercise ordinary care in the representation of Xarelto, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce, in that Defendants negligently misrepresented Xarelto's high risk of unreasonable, dangerous side effects.

229. Defendants breach their duty in representing Xarelto's serious side effects to the medical and healthcare community, to the Plaintiff's Decedent, the FDA and the public in general.

230. As a result of the foregoing acts and commissions, Plaintiff's Decedent was caused to suffer serious and dangerous side effects including a life-threatening bleed resulting in death, physical pain and mental anguish, diminished enjoyment of life, expenses for hospitalization and medical treatment, and loss of earnings.

231. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

AS AN ELEVENTH CAUSE OF ACTION: FRAUD

232. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

233. Defendants conducted research, or lack thereof, and used Xarelto as part of their research.

234. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff's Decedent, Plaintiff's Decedent's doctors, hospitals, healthcare professionals, and/or the FDA that Xarelto was safe and effective for use as a means to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery. Defendants also falsely stated that routine monitoring and blood tests were not necessary.

235. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiff's Decedent.

236. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff's Decedent, as well as Plaintiff's Decedent's respective healthcare providers and/or the FDA.

237. The information distributed to the public, the FDA, and the Plaintiff's Decedent, by Defendants, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

238. The information distributed to the public, the FDA, and the Plaintiff's Decedent, by Defendants intentionally included representations that Defendants' drug Xarelto was safe and effective for use to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

239. The information distributed to the public, the FDA, and the Plaintiff's Decedent, by Defendants intentionally included material representations that Defendants' drug Xarelto carried the same risks, hazards, and/or dangers as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

240. The information distributed to the public, the FDA, and the Plaintiff's Decedent, by Defendants intentionally included false representations that Xarelto was not injurious to the health and/or safety of its intended users.

241. The information distributed to the public, the FDA, and the Plaintiff's Decedent, by Defendants intentionally included false representations that Xarelto was a potentially injurious to the health and/or safety of its intended users, as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

242. These material representations were all false and misleading and were reasonably calculated to deceive.

243. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results no favorable to the Defendants, and results that demonstrated that Xarelto was not safe as a means of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, and/or was not as safe as other means of treatment for reducing the risk of stroke and systemic

embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

244. Defendants intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff's Decedent, regarding the safety of Xarelto, specifically but not limited to Xarelto not having dangerous and serious health and/or safety concerns.

245. Defendants intentionally made material representations to the FDA and the public in general, including the medical profession, and the Plaintiff's Decedent, regarding the safety of Xarelto, specifically but not limited to Xarelto being a safe means of reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

246. That it was the purpose of Defendants in marking these representations to deceive and defraud the public, the FDA, and/or the Plaintiff's Decedent, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff's Decedent, to falsely ensure the quality and fitness for use of Xarelto and induce the public, and/or the Plaintiff's Decedent to purchase, request, dispense, prescribe, recommend, and/or continue to use Xarelto.

247. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff's Decedent that Xarelto was fit and safe for use as treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of

recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

248. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff's Decedent that Xarelto was fit and safe for use as treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

249. Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff's Decedent that Xarelto did not present serious health and/or safety risks.

250. Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff's Decedent that Xarelto did not present health and/or safety risks greater than other oral forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

251. These representations and others made by Defendants were false when made, and/or were made with pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

252. These representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiff's Decedent, including Plaintiff's Decedent's respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff's Decedent and/or Plaintiff's Decedent's respective healthcare professionals to rely upon misrepresentation and caused the Plaintiff's Decedent to purchase, use rely on, request, dispense, recommend, and/or prescribe Xarelto.

253. Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Xarelto to the public at large, the Plaintiff's Decedent in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives, including other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

254. Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of Xarelto by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of Xarelto.

255. Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff's Decedent, as well as his respective healthcare professionals into a sense of security so that Plaintiff's Decedent would rely on the representations made by Defendants,

and purchase, use and rely on Xarelto and/or that Plaintiff's Decedent's respective healthcare providers would dispense, prescribe, and/or recommend the same.

256. Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff's Decedent, as well as Plaintiff's Decedent's respective healthcare professionals would rely upon the information being disseminated.

257. Defendants utilized direct to consumer adverting to market, promote, and/or advertise Xarelto and disseminate these false statements.

258. Plaintiff's Decedent and/or Plaintiff's Decedent's respective health care professionals did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, and were thereby induced to purchase, use and rely on Defendants' drug Xarelto.

259. At the time the representations were made, the Plaintiff's Decedent and/or Plaintiff's Decedent's respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Xarelto.

260. The Plaintiff's Decedent did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendants, nor could the Plaintiff's Decedent with reasonable diligence have discovered the true facts.

261. Had the Plaintiff's Decedent known the true facts with respect to the dangerous and serious health and/or safety concerns of Xarelto, Plaintiff's Decedent would not have purchased, used and/or relied on Defendant's drug Xarelto.

262. The Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff's Decedent.

263. As a result of the foregoing acts and commissions, Plaintiff's Decedent was caused to suffer serious and dangerous side effects including a life-threatening bleed resulting in death, physical pain and mental anguish, diminished enjoyment of life, expenses for hospitalization and medical treatment, and loss of earnings.

264. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

AS A TWELTH CAUSE OF ACTION: Violation of the North Carolina Consumer Fraud and Deceptive Business Practices Act (Violation of N.C.G.S. §§ 75-1.1 and 106-138)

265. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

266. Defendants engaged in consumer-oriented, commercial conduct by selling and advertising Xarelto.

267. Defendants misrepresented and omitted material information regarding the subject product by failing to disclose known risks.

268. Defendants misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation,

and/or knowing concealment, suppression, or omission of material facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of Xarelto, in violation of North Carolina General Statutes ("N.C.G.S.") §§ 75-1.1 and 106-138.

269. North Carolina has enacted statutes to protect consumers from deceptive, fraudulent, and unconscionable trade and business practices. Defendants violated these statutes by knowingly and falsely representing that the subject product was fit to be used for the purpose for which it was intended, when Defendants knew it was defective and dangerous, and by other acts alleged herein.

270. Defendants engaged in the deceptive acts and practices alleged herein in order to sell Xarelto to the public, including Plaintiff's Decedent.

271. As a direct and proximate result of Defendants violations of N.C.G.S. §§ 75-1.1 and 106-138, Plaintiff's Decedent has suffered damages, for which he is entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

272. As a direct and proximate result of Defendants violations of N.C.G.S. §§ 75-1.1 and 106-138 and other various consumer protection statutes enacted in other states and the District of Columbia, Plaintiff's Decedent has suffered damages, for which Plaintiff's Decedent is entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

273. Defendants uniformly communicated the purported benefits of Xarelto while failing to disclose the serious and dangerous side-effects related to the use of Xarelto, its safety, its efficacy, and its usefulness. Defendants made these representations to physicians, the medical

community at large, and to patients and consumers such as Plaintiff's Decedent in the marketing and advertising campaign described herein.

274. Defendants' conduct in connection with Xarelto was impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because Defendants misleadingly, falsely and/or deceptively misrepresented and omitted numerous material facts regarding, among other things, the utility, benefits, costs, safety, efficacy and advantages of Xarelto.

275. Defendants' conduct as described above was a material cause of Plaintiff's Decedent's decision to purchase Xarelto.

276. By reasons of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

REQUEST FOR PUNITIVE DAMAGES

277. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth, and further alleges as follows:

278. At all times relevant herein, Defendants:

a. Knew that Xarelto was dangerous and ineffective;

b. Concealed the dangers and health risks from Plaintiff's Decedent, physicians, pharmacists, other medical providers, the FDA, and the public at large;

c. Made misrepresentations to Plaintiff's Decedent, his physicians, pharmacists, hospitals and medical providers and the public in general as previously stated herein as to the safety and efficacy of Xarelto;

d. With full knowledge of the health risks associated with Xarelto and without adequate warnings of the same, manufactured, marketed, promoted, developed, sold and/or distributed Xarelto for routine use.

279. Defendants, by and through officers, directors, managing agents, authorized sales representatives, employees and/or other agents who engaged in malicious, fraudulent and

oppressive conduct towards Plaintiff's Decedent and the public, acted with willful and wanton and/or conscious and reckless disregard for the safety of Plaintiff's Decedent and the general public.

280. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff's Decedent suffered profound injuries and death that required medical treatment and incurred medical and hospital expenses.

DAMAGES

281. Plaintiff adopts and incorporates all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

282. Plaintiff seeks compensatory damages under the North Carolina Wrongful Death Act, N.C. Gen. Stat. § 28-A-18-2, in excess of $75,000, specifically including:

a. expenses for the care, treatment and hospitalization incident to the injuries resulting in Plaintiff's Decedent's death;

b. compensation for the pain and suffering of Plaintiff's Decedent prior to his death;

c. reasonable funeral expenses of the decedent; and

d. the present monetary value of Plaintiff's Decedent to him, including compensation for loss of his reasonably expected net income; services, protection, care and assistance; and society, companionship, comfort, guidance, kindly offices and advice.

283. Plaintiff seeks punitive damages pursuant to N.C. Gen. Stat. § 1D-1, *et seq*., due to the intentional, willful, and wanton misconduct of Defendants.

284. In the alternative, Plaintiff seeks treble damages as provided by N.C. Gen. Stat. § 75-16.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief as follows:

a. full refund of all costs associated with JD Woodard's use of Xarelto;

b. compensatory, consequential, treble and/or punitive damages, each individually in excess of $75,000;

c. attorney fees, expenses, interest, and costs of this action; and

d. such further relief as this Court deems necessary, just and proper.

JURY DEMAND

Demand is hereby made for trial by jury on all issues raised by these pleadings.

Respectfully submitted this 5th day of June, 2015.

MARTIN & JONES, PLLC

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